

Decisions taken in the 101st Meeting of the Genetic Engineering Approval Committee (GEAC) held on 09.06.2010.

The 101st meeting of the GEAC was held on 9.6.2010 in the Centre for Cellular and Molecular Biology (CCMB) at Hyderabad under the chairmanship of Shri M.F. Farooqui, Additional Secretary, MoEF and Chairman, GEAC.

The deliberations/decisions taken in the GEAC meeting in respect of Agenda items 4 to 7 are as follows:

Agenda item No. 4 : Policy issue

4.1 Report of the Sub-committee constituted by the GEAC to examine the "Guidance document for information/data generation and documentation for safety assessment of GE Plants" during BRL-I and II trials.

4.1.1 It was decided to consider the above report as part of the Bt brinjal review process. Accordingly, discussions on the above report were deferred. It was further agreed that the guidance document may be forwarded to the experts along with the background document.

4.1.2 The Chairman informed that in addition to experts/scientist suggested by the Minister in the decision document dated 09.02.2010, members may suggest names of other experts also. Some of the names suggested during the meeting include Dr Raghavendra Gadagkar, IISC, Bangalore, Dr V L Chopra, Member Planning Commission, Dr Sudhir Sopory, ICGEB, Dr Satyajit Rath, National Institute of Immunology and Dr Amitabh Joshi. JNCASR, Bangalore. It was agreed that these experts will also be consulted.

4.1.3 During the discussions, the Member Secretary suggested that the GEAC may consider development of a guidance document specific to Environment Risk Assessment of GM Crops by review of literature available at international level in this area and deliberations on the issues in a sub-committee to be constituted by the MoEF. The Committee supported the above suggestion.

4.2 Discussion on the draft proposal for setting up a National Centre for Assessment of GMOs prepared by Dr. P. M. Bhargava.

4.2.1 It was decided to consider the above proposal as part of the Bt brinjal review process. Accordingly, discussion on the above proposal was deferred.

Agenda item No. 5: Consideration of applications for confined field trials (Event selection, BRL-I and BRL-II) of transgenic crops expressing new genes as recommended by the RCGM.

5.1 **Permission to conduct event selection trials on transgenic groundnut events over expressing DREB2A for stress tolerance (drought and salt tolerance) by Department of Crop Physiology, University of Agricultural Sciences (UAS), Bangalore.**

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5.2 Permission to conduct event selection on transgenic groundnut events over expressing DREB1A for stress tolerance (drought tolerance) by Department of Crop Physiology, UAS, Bangalore.

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5.3 Permission to conduct event selection on transgenic groundnut events over expressing DREB1B for stress tolerance (drought tolerance) at UAS, Bangalore

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5.4 Permission to conduct event selection of transgenic groundnut over expressing PDH45 for stress tolerance (oxidative stress especially salt, cold & drought tolerance) at UAS, Bangalore.

5.1.1 The Committee noted that all four proposals at agenda items 5.1 to 5.4 pertain to the development of transgenic groundnuts being developed by UAS Bangalore to improve stress tolerance. It was noted that the request is to conduct event selection trials with the transgenic groundnuts developed by the institute. At the outset, the Committee requested Dr. Uday Kumar, Member, GEAC who is actively involved in the development of transgenic groundnut at UAS Bangalore, to leave the room to avoid any conflict of interest during the discussions.

5.1.2 The Committee noted that the transgenic groundnut to improve its stress tolerance; expresses three AP2-ERF-DREB transcription factors namely DREB2A, DREB1A, DREB 1B and PDH45, a DNA Helicase, respectively. It was further noted that two of the transgenic groundnuts expressing DREB2A and PDH45 have *gusA* gene in their expression cassettes. Members opined that biosafety issues that are to be addressed in respect of such transgenic crops are more complex as the transcriptional factors are known to trigger production of a large number of proteins downstream. These issues need to be further discussed and guidelines for biosafety testing need to be developed. The Committee was also of the view that because of the presence of gratuitous gene such as *gus* in the food crops, it may not be considered for environmental release when such a proposal is mooted by the project proponents.

5.1.3 After detailed deliberations, the Committee took the following decisions:

a. With regards to DREB1A and DREB1B groundnut transgenics; the Committee approved the request for event selection. However, the applicant was cautioned about the complexities associated with transcription factors as these are known to trigger production of a large number of proteins downstream which in turn raise issues in dealing with toxicology studies, etc; required for regulatory approval.

b. With regards to DREB2A and PDH groundnut transgenics; the Committee did not approve the request for event selection for eventual commercial development because both constructs contain *gus* gene. However, these are approved for contained research only.

5.5 Permission to conduct elite event selection trials on Glytol cotton (*Gossypium hirsutum*) hybrids during Kharif 2010 by M/s. Bayer Biosciences Pvt. Ltd. Gurgaon

5.5.1 The Committee noted that the request from M/s. Bayer Biosciences Pvt. Ltd; Is to conduct elite event selection trials with Glytol cotton (*Gossypium hirsutum*) hybrids containing *2mEPSPS* gene event The objective of these trials is to evaluate the herbicide tolerant cotton hybrids by spraying Glyphosate herbicide. The Committee noted that the above proposal has been recommended by the RCGM in its meeting held on 20.04.2010.

On examining the application, it was observed that pages 33 to 37 pertaining to crucial information on plasmid/construct/ transformation vector, etc, were missing.

5.5.2 The Committee decided to obtain complete information from the RCGM before considering the proposal.

5.6 Permission to conduct second year Biosafety Research Level-1 (BRL-1) trials with transgenic maize (*Zea mays*) hybrids namely TC-1 and TC-2 containing *cry1F* gene (Event TC1507 (DAS-01507-1)) by M/s. Dow Agrosciences India Pvt. Ltd., Mumbai for

5.6.1 The Committee noted that the request from M/s Dow Agrosciences India Pvt. Ltd., is to conduct second year BRL-I trials with transgenic maize (*Zea mays*) hybrids namely TC-1 and TC-2 containing *cry1F* gene (Event TC1507 (DAS-01507-1)) at Coimbatore and Bhavani Sagar in TNAU; and Balajigapade and Kathalgeri in UAS, Bangalore during Kharif 2010 for biosafety, bio-efficacy and agronomy evaluation.

5.6.2 The Committee also noted that RCGM in its 88th meeting held on 20.04.2010 has advised the applicant *“to ensure the comparison of the hybrids with controls in areas with insect infestation. However, if very low incidence of insect infestation is observed in trial locations, the applicant may explore the possibility of artificial introduction of pests. The applicant should also ensure generation of required safety data in parallel to the conduct of BRL-I trials”*.

5.6.3 After detailed deliberations and based on recommendations of the RCGM, the Committee approved the request to conduct second year BRL-I trials with transgenic maize (*Zea mays*) hybrids, namely TC-1 and TC-2 containing *cry1F* gene (Event TC1507 (DAS-01507-1)) at Coimbatore and Bhavani Sagar in TNAU; and Balajigapade and Kathalgeri in UAS, Bangalore in confined conditions.

5.7 Permission to conduct second year Biosafety Research Level-1 (BRL-1) trials with WideStrike™ cotton hybrids by M/s. Dow Agrosciences India Pvt. Ltd

5.7.1 The Committee considered the request from M/s. Dow Agrosciences India Pvt. Ltd., Mumbai to conduct second year BRL-1 trials with WideStrike™ cotton hybrids namely WS103 & WS106 containing *cry1F* (Event 281-24-236+ *cry1Ac* (Event 3006-210-23) at Aurangabad and Vadodara, in Central zone during Kharif 2010 for biosafety, bio-efficacy and agronomy evaluation.

5.7.2 The Committee also noted that the RCGM in its 88th meeting held on 20.04.2010. RCGM has advised the applicant *“to ensure the comparison of the hybrids with controls in areas with insect infestation. However, if very low incidence of insect infestation is observed in trial locations, the applicant may explore the possibility of artificial introduction of pests. The applicant should also ensure generation of required safety data in parallel to the conduct of BRL-I trials. RCGM also advised the applicant to include Bollgard II containing two stacked genes viz. *cry1Ac* and *cry2Ab2* as an additional check in the trials”*.

5.7.3 After detailed deliberations and based on recommendations of the RCGM, the Committee approved the request to conduct second year BRL-1 trials with WideStrike™ cotton hybrids, namely WS103 & WS106 containing *cry1F* (Event 281-24-236+ *cry1Ac* (Event 3006-210-23) at Aurangabad and Vadodara, in Central zone in confined conditions.

Agenda Item No 6: Information items.

6.1 Request from Ministry of Health and Family Welfare.

6.1.1 The Committee noted that the Department of Ayush, Ministry of Health and Family Welfare has requested MoEF to co-opt the Chief Executive Officer, National Medicinal Plants Board; Adviser (Ayurveda) Department of Ayush; and Director General, Central Council for Research in Unani Medicine to the GEAC or to give them a hearing about the concerns of the department pertaining to commercialization of transgenic medicinal plants.

6.1.2. The Committee agreed to invite representatives of the concerned departments to the next GEAC meeting to give them an opportunity for a personal hearing about their concerns on transgenic medicinal plants.

Agenda Item No 7: Any other matter with the permission of the Chair.

7.1 Representations from M/s Mahyco regarding two years of BRL-II trials with BGII RRflex cotton and seed production.

7.1.1 In accordance with the decisions taken in the GEAC meeting held on 12.05.2010, M/s Mahyco has been advised to conduct two years of BRL-II trials with BGII RRflex cotton. The company has requested the GEAC to reconsider its decision on conduct of two years of BRL-II trials with BGII RRflex on the grounds that the 'Guidelines and Standard Operating Procedures (SOPs) for Confined Field Trials of Regulated Genetically Engineered (GE) Plants' which have been adopted by RCGM and GEAC, stipulate only three years of confined field trials (either two years of BRL-I trials and one year of BRL-II trials or one year of BRL-I trials or two years of BRL-II trials).

7.1.2 After detailed deliberations, the Committee decided that in all future cases a minimum of two years BRL-II trials shall be conducted. As far BRL-I is concerned, decision on whether one year of BRL-I or two years of BRL-I is required shall be based on the data generated during the first year of BRL-I trials.

7.1.3 The Committee also considered the representation from the company requesting for seed production in 25 acres per hybrid per zone. The Committee agreed to the request subject to the condition that seed production area of 25 acres should not be spread in more than five locations per zone.
